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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,591	12/21/2001	Eugene Medlock	01017/37128C	6379
4743	7590	03/23/2004	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP			JIANG, DONG	
6300 SEARS TOWER			ART UNIT	
233 S. WACKER DRIVE			PAPER NUMBER	
CHICAGO, IL 60606			1646	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/037,591	Applicant(s) MEDLOCK ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-8, 10, 12, 57-59, 66 and 79 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10, 57-59 and 79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/23/03</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED OFFICE ACTION**

Applicant's amendment filed on 23 December 2003 is acknowledged and entered. Following the amendment, claims 1-3, 9, 11, 13-56, 60-65, and 67-78 are canceled, claims 4, 57 and 66 are amended, and the new claim 79 is added.

Currently, claims 4-8, 10, 12, 57-59, 66 and 79 are pending, and claims 4-8, 10, 57-59 and 79 are under consideration.

#### **Withdrawal of Objections and Rejections:**

The objection of the specification is withdrawn in view of applicant's amendment.

All objections and rejections of claims 1-3 and 11 are moot as applicants have canceled the claims.

The provisional statutory type double patenting rejection of claims 1-8, 10, 11 and 57-59 under 35 U.S.C. 101 is withdrawn in view of applicant's argument that the copending Application 09/886,404 is abandoned.

The rejection of claims 4, 5, 7, 11 and 57 under 35 U.S.C. 102(b) as being anticipated by Marra et al. for locus W88186 (EST, 12 September 1996) is withdrawn in view of applicant's amendment.

#### **Formal Matters:**

##### ***Priority Determination***

This application claims priority to US applications 09/868,404 and 09/810,384, and US provisional applications 60/213,125 and 60/266,159. The claimed priority to US provisional application 60/213,125 has been denied for reasons of record set forth in the last Office Action, paper No. 16, mailed on 19 June 2003, as it does not satisfy the utility/enablement requirement of 35 U.S.C. 101/112, first paragraph.

Applicants argument, filed on 23 December 2003 has been fully considered, but is not deemed persuasive for reasons below.

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At page 17 of the response, the applicant argues that the disclosure in the provisional application 60/213,125 state that the IL-17 like polynucleotides and polypeptides of the present invention are useful for the treatment or diagnosis immune disorders, inhibiting T cell proliferation and activation, and B cell proliferation and Ig secretion, and that they would be useful for modulating hematopoietic cell growth, and may be useful in treating or diagnosing tumors, and therefore, the '125 specification expressly provides patentable utilities that is specific, substantial and credible. This argument is not persuasive for the reasons below. First, the Examiner is not able to locate the above utility statement in the indicated locations in the specification as pointed out by applicants. Further, it is noted on page 98, lines 8-12, the specification states that it has been found that the present IL-17 like nucleic acids, polypeptides, and *agonists and antagonists* of the invention can increase bone marrow and spleen cellularity, eosinophils, and CFCs, and decrease lymphocyte production. As such, it is unclear whether it is IL-17 like polypeptides and agonists, or the antagonists that have the stated functional activity. The biological effects of the agonists and antagonists are mutually exclusive, and only one of them might have the stated activity. Such a statement indicates a "guess" rather than assertion of utility, and does not constitute an assertion of a specific and substantial utility.

**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-8, 10, 57-59 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 is indefinite. Part (f) of the claim recites hybridization conditions as "wherein the conditions for *hybridization and washing* are 0.015M sodium chloride, 0.0015 sodium citrate at 65-68 °C *or* 0.0015 sodium citrate". It is unclear which part of the recitation is directed to hybridization conditions, and which part of the recitation is directed to washing conditions. Also, it is unclear what the term "or" is meant, and whether the first part before "or" is the condition for hybridization, which is not the art recognized hybridization conditions. The claim

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is further indefinite for missing the unit for the reagents used in the hybridization. The metes and bounds of the claim, therefore, cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-8, 10, and 57-59 remain rejected, and the new claim 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a nucleic acid of SEQ ID NO:1, and a nucleic acid encoding a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for claims to a hybridization variant thereof under stringent conditions (claim 79, part (f)). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the last Office Action, paper No. 16, at pages 6-8.

Applicants argument, filed on 23 December 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 21 of the response, the applicant argues that techniques for identifying nucleic acids hybridizing under stringent conditions are well known in the art, and the specification provides methods for carrying out the hybridization reactions. This argument is not persuasive because the issue is not whether the hybridization method is known in the art, rather, the issue is [that the claim encompasses molecules which may share certain functional properties of SEQ ID NO:2, but may be structurally distinct from the polypeptide of SEQ ID NO:2, because hybridization will occur even under stringent conditions between two molecules sharing only local identity, which sequences might be totally divergent outside of that region. Such hybridized molecules may encode proteins capable of inducing TNF- $\alpha$  or IL-6, yet have other distinct biological functions from those of SEQ ID NO:2. The specification does not define a specific hybridization condition for obtaining the claimed species, or working examples of any

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such variants, which would be within the limitations of the claims. Therefore, it would require undue experimentation in order to make the claimed invention in its full scope.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 4-8, 10, and 57-59 remain rejected, and the new claim 79 is rejected under 35 U.S.C. 102(a) as being anticipated by Gorman et al, WO200042187, for the reasons of record set forth in the last Office Action, paper No. 16, at page 10.

Applicants argument, filed on 23 December 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 24 of the response, the applicant argues that the present application is entitled to the filing date of the provisional application 60/213,125, and thus, the Gorman reference is not prior art against any of the pending claims. This argument is not persuasive for the reasons addressed above under "Priority Determination".

Claims 4-8, 10, 57-59 and 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al. (US6,562,578, provided by applicants), for the same reasons set forth in the rejection above, by Gorman et al, WO200042187 (see the last Office Action, paper No. 16, at page 10), as the relevant teachings are the same in both references of Gorman et al, WO200042187 and Gorman et al., US6,562,578.

**Conclusion:**

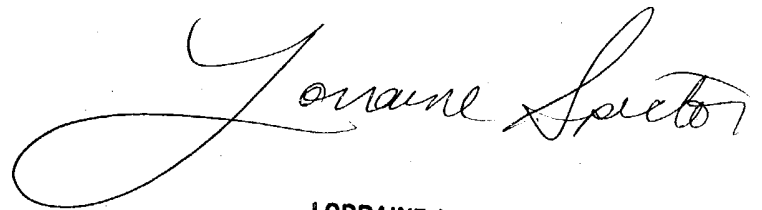
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above a typed name and title.

LORRAINE SPECTOR  
PRIMARY EXAMINER

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
3/8/04